

7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding ethylene glycol and propylene glycol in air, water, and other media are summarized in Tables 7-1 and 7-2.

An MRL of 0.5 ppm has been derived for acute-duration inhalation exposure (14 days or less) to ethylene glycol, based on a NOAEL of 197 ppm for increased renal weight (Tyl 1988a).

An MRL of 2.0 mg/kg/day has been derived for acute-duration oral exposure (14 days or less) to ethylene glycol, based on a NOAEL of 150 mg/kg/day for developmental toxicity (skeletal alterations) (Tyl 1989).

An MRL of 2.0 mg/kg/day has been derived for chronic-duration exposure (365 days or more) to ethylene glycol, based on a NOAEL of 200 mg/kg/day for the renal toxicity in rats (DePass et al. 1986a; Woodside 1982).

An MRL of 0.009 ppm has been derived for intermediate-duration inhalation exposure (1.5-364 days) to propylene glycol based on a LOAEL of 51 ppm for nasal hemorrhaging (Suber et al. 1989).

EPA (IRIS 1994) assigned ethylene glycol a reference dose (RfD) of 2.0 mg/kg/day with an uncertainty factor of 100 based on kidney toxicity in rats (DePass et al. 1986).

Ethylene glycol is on the list of chemicals appearing in “Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986” (EPA 1987b, 1987c). Comprehensive Environmental Response Compensation and Liability Act (CERCLA or Superfund) regulations require that accidental releases greater than 5,000 pounds of ethylene glycol be reported (EPA 1993a).

Both ethylene glycol and propylene glycol are regulated under Clean Air Act New Source Performance Standards for the synthetic organic chemical manufacturing industry (EPA 1993b).

Propylene glycol and ethylene glycol are regulated by the Clean Water Act Effluent Guidelines for organic chemicals, plastics, and synthetic fibers (OCPSF). The waste water generated by the

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production of these chemicals has effluent limitations on biochemical oxygen demand (BOD₅), total suspended solids (TSS), and pH (EPA 1987d).

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Table 7-1. Regulations and Guidelines Applicable to Ethylene Glycol

Agency	Description	Information	References
<u>NATIONAL</u>			
Regulations:			
a. Air:			
OSHA	Meets Criteria for Medical Records	Yes	29 CFR 1910.20 OSHA 1987 OSHA 1988
EPA	Hazardous Air Pollutants	Yes	U.S. Congress 1990
EPA OAR	App. A - Chemicals Defining Synthetic Organic Chemical and Polymer Manufacturing	Yes	40 CFR 52 EPA 1972a
	Subpart VV - Std. of Performance for Equipment Leaks of VOC in SOCM: Chemicals Produced by Affected Facilities	Yes	40 CFR 60.489 EPA 1983
	Definitions of Emissions from Polymer Manufacturers: Definition of "Polymerization Reaction Section"	Yes	40 CFR 60.561 EPA 1990b
	Subpart NNN - Std. of Performance for VOC Emissions from SOCM: Distillation Operations: Chemical Affected	Yes	40 CFR 60.667 EPA 1990b
	Subpart RRR - Std. of Performance for VOC Emissions from SOCM: Process Reactors: Chemicals Affected	Yes	40 CFR 60.707 EPA 1993b
b. Water			
EPA OW	Commodity Organic Chemical Subcategory	Yes	40 CFR 414.60 EPA 1987d
c. Food:			
FDA	Indirect Food Additive for Use only As a Component of Adhesives.	Yes	21 CFR 175.105 FDA 1977a FDA 1977b
	2,4-D: Food Tolerances for Residues		40 CFR 180.142 EPA 1982
	2,4-D Applied in the Form of Polyethylene Glycol and/or Propylene Glycol		
	Max. 2,4-D tolerance: Pasture and Rangeland Grasses	1000 ppm	
	Min. 2,4-D tolerance: Blueberries and Rice	0.1 ppm	
d. Other:			
EPA OERR	Toxic Chemical Release: Community Right to Know	Yes	40 CFR 372.65 EPA 1987b EPA 1987c
EPA	Reportable Quantity	5,000 lbs.	58 FR 54836 EPA 1993a

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Table 7-1. Regulations and Guidelines Applicable to Ethylene Glycol (continued)

Agency	Description	Information	References
<u>NATIONAL (cont.)</u>			
EPA OPTS	Premanufacture Notification Exemptions: Polymers - List of Reactants From Which Polyesters May be Made	Yes	40 CFR 723.250 EPA 1984b
Guidelines:			
a. Air:			
ACGIH	Ceiling Limit	127 mg/m ³ (50 ppm)	ACGIH 1994
EPA	Drinking Water Quality Guidelines	7,000 µg/L	FSTRAC 1990
NRC/NAS	Emergency Exposure Guidance Level	40 ppm (1 hour) 20 ppm (24 hours)	NRC 1994
b. Other:			
	RfD (oral)	2.0 mg/kg/day	IRIS 1994
	Carcinogenic Classification	No data	
	Unit risk (air)	No data	
	Unit risk (water)	No data	
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:			
	Acceptable ambient air concentrations		
	8 hours		
FL-Pinellas	24 hours	1.27x10 ⁻³ µg/m ³	Florida 1994
	8 hours	3.048x10 ⁻² µg/m ³	
LA	24 hours	3.02x10 ⁻³ µg/m ³	NATICH 1991
MA	Annual	3.45x10 ⁻¹ µg/m ³	
	1 hour	3.45x10 ⁻¹	
ND	8 hours	1.27 mg/m ³	
NV	24 hours	2.98 mg/m ³	
OK	24 hours	1.27x10 ⁻⁴ µg/m ³	
VA	24 hours	1.1x10 ⁻³ µg/m ³	
WA-SWEST		4.16x10 ⁻² µg/m ³	
<u>STATE (cont.)</u>			
KY	Significant Emission Levels of Toxic Air Pollutants	2.240x10 ⁻² lbs/hour	401 KAR 63.022 NREPC 1986
	Effects Screening Level		
TX	30 minutes	260 µg/m ³	Texas 1994
	Annual	26 µg/m ³	
b. Water:			
	Drinking Water Quality Guidelines and Standards		FSTRAC 1990
AZ		5,500 µg/L	
CT		100 µg/L	
ME		5,500 µg/L	
MA		5,500 µg/L	
MN		14,000 µg/L	
NH		7,000 µg/L	
NJ		290 µg/L (future)	

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Table 7-1. Regulations and Guidelines Applicable to Ethylene Glycol (continued)

Agency	Description	Information	References
<u>STATE (Cont.)</u>			
RI		7,000 µg/L	
VT		7 µg/L (standard)	
	Water Quality: Human Health		CELDs 1994
CO	Domestic water supply-gw	7,000 µg/L	
CT	Drinking water supply-action level	100 µg/L	
ME	Drinking water standards - misc. organic chemicals screening level number 2 - To be analyzed at state discretion, depending on results of screening level 1	Yes	
NH	Drinking water quality standards (MCLs) SNARLS Toxic contaminant levels: Length of exposure (1 day) Length of exposure (lifetime)	Yes 19 mg/L 5.5 mg/L	
	Water Quality: Aquatic Life		CELDs 1994
OH	Criteria for Aquatic Life Habitat Use: Coldwater, outside mixing zone, max. 30-day average Coldwater inside mixing zone, max.	 160 µg/L 7.2 µg/L 320 µg/L	
	Limited Resource warm water Outside mixing zone, max. Inside maximum zone, max.	 160 µg/L 320 µg/L	
	Groundwater Quality Standards		CELDs 1994
CO	Human Health	7,000 µg/L	
NC	Water Quality Standards (drinking water supply) Class GS waters	 7.0 mg/L	
WI	Public Human Health Enforcement standard Preventive Action Limit	 7 mg/L 0.7 mg/L	
VT	Enforcement standard Preventive action limit	 7.5 mg/L 3.5 mg/L	VANR 1988
	Hazardous Constituents		CELDs 1994
NJ	Listed as hazardous substance (in relation to drinking water systems)	Yes	
VT	Hazardous waste from non-specific sources. Vermont listed wastes (VT08) "waste ethylene glycol based coolants, antifreezes, and solutions containing greater than 700 ppm of ethylene glycol" toxic waste	Yes	

ACGIH = American Conference of Governmental Industrial Hygienists; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FSTRAC = Federal-State Toxicology and Regulatory Alliance Committee; IRIS = Integrated Risk Information System; MCL = Maximum Contaminant Level; NRC/NAS = National Research Council/National Academy of Sciences; OAR = Office of Air and Radiation; OERR = Office of Emergency and Remedial Response; OPTS = Office of Pesticides and Toxic Substances; OSW = Office of Solid Wastes; OW = Office of Water; RfD = Reference Dose; SNARL = Suggested No Adverse Response Level; SOCMI = Synthetic Organic Chemicals Manufacturing Industry; VOC = Volatile Organic Compound; WHO = World Health Organization

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Table 7-2. Regulations and Guidelines Applicable to Propylene Glycol

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
WHO	Acceptable Daily Intake	0-25 mg/kg	FAO/WHO 1974
<u>NATIONAL</u>			
Regulations:			
a. Air			
EPA OAR	App. A - Chemicals Defining Synthetic Organic Chemical and Polymer Manufacturing	Yes	40 CFR 52 EPA 1972a
	Subpart VV - Std. of Performance for Equipment Leaks of VOC in SOCM: Chemicals Produced by Affected Facilities	Yes	40 CFR 60.489 EPA 1983
	Definitions of Emissions from Polymer Manufacturers: Definition of "Polymerization Reaction Section"	Yes	40 CFR 60.561 EPA 1990b
	Subpart NNN - Std. of Performance for VOC Emissions from SOCM Distillation Operations: Chemical Affected	Yes	40 CFR 60.667 EPA 1990b
	Subpart RRR - Std. of Performance for VOC Emissions from SOCM Process Reactors: Chemicals Affected	Yes	40 CFR 60.707 EPA 1993b
	New Source Performance Standard	Yes	58 FR 45962 EPA 1993c
b. Water			
EPA OW	Bulk Organic Chemicals Under the Clean Water Act	Yes	40 CFR 414.70 EPA 1987d
	App. A - Non-Complexed Metal-bearing Waste	Yes	40 CFR 414 EPA 1987d
EPA OWRS	Pesticide subject to registration and reregistration	Yes	40 CFR 152.146 EPA 1989b EPA 1989a
c. Food:			
FDA	Generally Recognized as Safe	Yes	21 CFR 184.1666 FDA 1982
	2,4-D: Food Tolerances for Residues		40 CFR 180.142 EPA 1982
	2,4-D Applied in the Form of Polyethylene Glycol and/or Propylene Glycol		
	Max. 2,4-D tolerance: Pasture and Rangeland Grasses	1000 ppm	
	Min. 2,4-D tolerance: Blueberries and Rice	0.1 ppm	
	Inert Ingredients Exempt From Tolerances	Yes	40 CFR 180.1001 EPA 1971
d. Other:			
EPA OPTS	Temperature Correction Factors for Organic Solvents	0.043 K°C/mmHg	40 CFR 796.1220 EPA 1985a

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Table 7-2. Regulations and Guidelines Applicable to Propylene Glycol (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
	Avian Dietary Testing Procedures - Sample Diluents	Yes	40 CFR 797.2050 EPA 1985b
	Sample Diluents for Bobwhite Reproductive Tests	Yes	40 CFR 797.2130 EPA 1985b
	Sample Diluents for Mallard Reproductive Tests	Yes	40 CFR 797.2150 EPA 1985b
	Sample Carriers for Avian Acute Toxicity Test	Yes	40 CFR 797.2175 EPA 1985b
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:	Acceptable ambient air concentrations		
VA	24 hours	1.10x10 ³ µg/m ³	NATICH 1991

EPA = Environmental Protection Agency; FDA = Food and Drug Administration; NATICH = National Air Toxics Information Clearinghouse; OAR = Office of Air and Radiation; OPTS = Office of Pesticides and Toxic Substances; OW = Office of Water; OWRS = Office of Waste Regulations and Standards; SOCMI = Synthetic Organic Chemical Manufacturing Industry; VOC = Volatile Organic Compound

